

V/amed + VST

Internal Audit Check list			
PRODUCTION			
Created:	17/May 1995	Audit No 15	VOP 08
Revised:	11 May 2021		Page 1 of 5
Audit Date	11-5-21	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 7.1.3	<b>Infrastructure</b> The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology.	Regular Review
VST Ltd ISO9001:2015 8.5.1	<b>Control of production and service provision</b> The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities	Infrastructure Doc index Rolling tasks + Analysis
Viamed Ltd ISO13485:2016 6.3	<b>Infrastructure</b> The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities,	Reviews Issues

	<p>when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.</p> <p>Records of such maintenance shall be maintained</p>	
<p>Viamed Ltd ISO13485:2016 7.5.1</p>	<p><b>Control of production and service provision</b></p> <p>Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to:</p> <ul style="list-style-type: none"> <li>a) documentation of procedures and methods for the control of production (see 4.2.4);</li> <li>b) qualification of infrastructure;</li> <li>c) implementation of monitoring and measurement of process parameters and product characteristics;</li> <li>d) availability and use of monitoring and measuring equipment;</li> <li>e) implementation of defined operations for labelling and packaging;</li> <li>f) implementation of product release, delivery and post-delivery activities.</li> </ul> <p>The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.</p>	<p>Regular Reviews</p> <p>infrastructure</p>
<p>Viamed Ltd ISO13485:2016 8.2.4</p>	<p><b>Internal audit</b></p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system:</p> <ul style="list-style-type: none"> <li>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</li> <li>b) is effectively implemented and maintained.</li> </ul> <p>The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.</p> <p>An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.</p> <p>Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5).</p> <p>The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.</p> <p>NOTE Further information can be found in ISO 19011.</p>	<p>infrastructure audit calendar Doc index</p>
<p>Viamed Ltd ISO13485:2016</p>	<p><b>Monitoring and measurement of product</b></p> <p>The organization shall monitor and measure the characteristics of the</p>	



16 8.2.6	<p>product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.</p> <p>Evidence of conformity with the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the test equipment used to perform measurement activities.</p> <p>Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed.</p> <p>For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.</p>	inba steds
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	QUESTION:	RESPONSE	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	#175458, 175463 198192 #225503	
2	Check that each job for production has its own unique worksheet in the ducket.		Y
3	Does the worksheet contain all the relevant information.		X
4	Check that all jobs are kept in an appropriate duckets.		Y
5	Check that jobs awaiting assembly are in the correct area.	Production jobs are usually released one at a time. These are worked on at time of release.	Y
6	<p>Verify that all parts are correctly scanned to the production build by the operator.</p> <p>Use the PS production number from a production job in a ducket or from the all jobs list and then put it into - Production - Parts pick. This list can then be compared to the stock procedure - Parts List to Build batch.</p> <p>Check 5 to see if what is scanned matches what is required.</p> <p>1. 3177-VST-8000004- ✓ - 13737</p> <p>2. 3173-VIA-0110437- ✓ - 21266</p> <p>3. 3196-VIA-0121215- ✓ - X</p> <p>4. 3176-VST-8030451- ✓ - X</p> <p>5. 3191-VIA-0012167- ✓ - X</p> <p>* m/p/c/d/r/p/c #231340</p>	<p>break down full case to back panel</p> <p>#231347</p>	No
7	Check that the operating procedure is with the job, and is the latest issue.	Intrastats links to production COPS	N/A Y
8	Verify that the operator has adequate training and / or experience.	Training Audit	N/A Y
9	Verify that there is adequate tooling to complete the task.		Y

must have procedure for all production  
Also must have part numbers in Description.

10	Check that completed jobs are in the correct area.		Y
11	Verify that all the relevant information is entered into Intrastats. Check 5 production jobs. Use the same as above to find a barcode ID from each Production job and check its QA history. <i>QA</i> 1. 3177- ✓ 2. 3173- ✓ 3. 3196- ✓ 4. 3176- ✓ 5. 3191- ✓		Y
12	Check the Start Job List in Production to see if they are all valid. Review any older than a month. List any below. <i>both VST</i>	<i>3180 28/5/21 ✓ 3179 28/5/21 ✓ within month</i>	Y
13	Check the Production in Production List, in production. The list shows what is in and at what stage it is at. Review any older than a month. List any below.	<i>1 test PS-2602 N/A - internal all Rest in terms</i>	Y
14	Check that finished product is placed in the correct area for test.	Tested at time of production	Y
15	Is there adequate storage and working facilities.		Y
16	Is the production area in a tidy and workable state.		X
17	Can resources be improved to facilitate process control.		No

### Sub Processes Linked to Audit

Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

### Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 6955 To set production job for any stock item that is needed for customer back order, warehouse requests or marketing	907 Director 3 (Steve)	908 Managing Director	Freq 2 Risk 1 Overall 2	Task 1W Audit 1M	
	<i>221984 in terms</i>	<i>221985 ✓</i>			

## Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7727 To carry out Audit 15 Production Viamed		28 221164 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	This Audit
PROCESSID 7775 To carry out Audit 15 Production VST		175 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

## Production Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7736 When a new production is needed we the production job to the list of procedures.	553 Goods Out	554 Managing Director	Freq 3 Risk 4 Overall 12	Task 1M Audit 3M	

Check to make sure that every new job has a procedure linked to it.

PROCESSID 7737 Review the Production List, check and list those items that were started more than 30 days ago have not been through QA.	556 Managing Director	557 Company Secretary	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M	
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Audit is carried out and production is reviewed and chased at this point.

PROCESSID 7738 Production Review, Identify any production jobs taking a long amount of time	551 Managing Director	552 Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
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